**NOT FOR PUBLICATION**

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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| MEDPOINTE HEALTHCARE INC. | : | CIVIL ACTION NO. 03-5550 (MLC) |
| Plaintiff, | : | **MEMORANDUM OPINION** |
| v. | : | |
| HI-TECH PHARMACAL CO., INC. | : | |
| Defendant. | : | |

**COOPER, District Judge**

Plaintiff, MedPointe Healthcare Inc. ("MedPointe"), commenced this action against defendant, Hi-Tech Pharmacal Co., Inc. ("Hi-Tech"), alleging, inter alia, that Hi-Tech's Tannate-12DS product infringes upon its United States Patent No. 6,417,206 (the "'206 patent"). (Dkt. entry no. 1, Compl.) Hi-Tech asserted various affirmative defenses to MedPointe's claims, including that the '206 patent was obtained by inequitable conduct and on the basis of unclean hands. (Dkt. entry no. 82, Am. Ans. & Counterclaim.) Further, Hi-Tech asserted a counterclaim against MedPointe alleging, inter alia, that the '206 patent is invalid because (1) it claims an invention that would have been obvious to persons skilled in the art, and thus, was unpatentable pursuant to 35 U.S.C. § ("Section") 103(a), (2) it was obtained as a result of MedPointe engaging in a pattern of inequitable conduct, and (3) MedPointe has unclean hands and has misused the '206 patent. (Id.)

MedPointe cross-moved for summary judgment on Hi-Tech's unclean hands and patent misuse allegations. (Dkt. entry no. 88.) MedPointe separately cross-moved for summary judgment on Hi-Tech's inequitable conduct allegations. (Dkt. entry no. 89.) Thereafter, Hi-Tech sent a letter to this Court indicating that it no longer intended to pursue either its unclean hands and patent misuse, or its inequitable conduct defenses. (Dkt. entry no. 92.) Thus, MedPointe's separate cross motions for summary judgment on these issues are moot.

Hi-Tech moves for summary judgment on its counterclaim allegation that claims 1, 5-8, and 12-14 of the '206 patent were invalid for obviousness under Section 103.[1] (Dkt. entry no. 87.) The Court conducted oral argument on November 30, 2006. (Dkt. entry no. 119.) For the reasons stated herein, the Court will deny that motion.

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[1] MedPointe also commenced an action against Morton Grove Pharmaceuticals, Inc. ("Morton Grove") alleging, inter alia, that Morton Grove's Tannihist-12D Suspension product infringes upon its '206 patent. (Civ. Case No. 04-1686, dkt. entry no. 1, Compl.) The Morton Grove action was consolidated with the present action for discovery and case management purposes only. (See dkt. entry no. 59, Superseding Scheduling Order, at ¶ 1.) After Hi-Tech filed its motion for summary judgment, Morton Grove sent letters to this Court indicating that it obtained Hi-Tech's consent to join in the motion and all briefs and other documents submitted in support of the motion. (Civil Case No. 04-1686, dkt. entry nos. 59 & 81.) However, Morton Grove did not file a separate motion in Civil Action Number 04-1686, and thus, there is no other motion for summary judgment on the validity of the '206 patent currently pending before this Court.

## BACKGROUND

### I. MedPointe and the '206 Patent

MedPointe is a Delaware corporation that markets and sells cough and cold medications. (Compl., at ¶ 1.A; Pl. Br., at 2.) It was known as Carter-Wallace, Inc. until October 2001. (Pl. Br., at 2.) MedPointe is the owner-assignee of the '206 patent, which was issued on July 9, 2002. (Compl., at ¶ 6.) Prior to filing its application for the '206 patent, MedPointe filed at least five other patent applications, which claimed various combinations of tannate antitussives, antihistamines, and decongestants. (Pl. Br., at 3.)

The '206 patent discloses a combination of tannate salts to be orally administered "for the symptomatic relief of cough associated with respiratory tract conditions such as the common cold, bronchial asthma, acute and chronic bronchitis." (Compl., Ex. A, '206 patent, Abstract.) It is composed of fourteen claims, but only claim 1 is independent. (See id. at col. 4.) Claim 1 states:

> 1. A therapeutic composition for the symptomatic relief of cough associated with adverse respiratory tract conditions in warm-blooded animals in need of such treatment said composition comprising pharmaceutically effective amounts of active ingredients, wherein said active ingredients consist of carbetapentane tannate, pyrilamine tannate and phenylephrine tannate.

(Id. at col. 4, lines 15-21.) Claim 8 is a dependent method claim covering the administration of the composition in claim 1.

(Id. at col. 4, lines 41-45.) Claims 2 through 4 address the composition in tablet form, and claims 9 through 11 address the method of administering same. (Id. at col. 4, lines 22-30 & 46-54.) Further, claims 5 through 7 address the composition in suspension form, and claims 12 through 14 address the method of administering same.[2] (Id. at col. 4, lines 31-40 & 55-64.)

The asserted innovation of the '206 patent is the novel combination of carbetapentane tannate, pyrilamine tannate, and phenylephrine tannate, which produces a compound with better antihistaminic and sympathomimetic decongestant properties than each of these tannates have when used alone. (Id. at col. 2, lines 21-26.) Combining tannate salts is very desirable because "such salts are generally stable and may be combined in such form without any untoward side effects." (Id. at col. 2, lines 2-3.) Further, tannate salts are medically desirable because they absorb slowly, and thus, have a long and sustained effect. (Def. Br., at 2.)

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[2] Dependent claims 4 and 11, and 7 and 14, respectively dealing with tablets and suspensions, address the dosages of the active ingredients: 60 mg and 30 mg/5 ml, carbetapentane tannate; 40 mg and 30 mg/5 ml, pyrilamine tannate; 10 mg and 5 mg/5 ml phenylephrine tannate. (Id. at col. 4, lines 27-30, 37-40, 51-54, & 61-64.) Dependent claims 3 and 10, and 6 and 13, respectively address the dosages of the active ingredients, which are characterized as ranges with the middle generally being the same value given in the prior set of claims. (Id. at col. 4, lines 23-26, 33-36, 48-50, & 57-60.)

MedPointe released its commercial embodiment of the '206 patent, Tussi-12D, in the fall of 2002. (Id. at 5.) However, MedPointe and its predecessor, Carter-Wallace, had previously marketed other cough and cold products containing tannate salt combinations, including Tussi-12. (Id. at 2-3.) MedPointe did not clinically test Tussi-12D or seek FDA approval before releasing it because all three of its active ingredients were "grandfathered 'DESI' drugs" that the FDA had recognized as safe for human use. (Id. at 5.) Although Tussi-12 (Original) and Tussi-12 (Reformulated) continue to be sold, most customers prefer Tussi-12D. (Def. Resp. & Counterstatement to Pl. Statement of Uncontested Facts, at 39.)

**II. Hi-Tech and Tannate-12DS**

Hi-Tech is a New York corporation that also markets and sells cough and cold medications. (Am. Ans. & Counterclaim, at ¶ 1B; Def. Br., at 5.) Hi-Tech has marketed various cough and cold medications containing tannate salts, including Tannate 12, a generic version of MedPointe's Tussi-12. (Def. Br., at 5.) In 2003, Hi-Tech began marketing its Tannate-12DS product, which it represented as a generic substitute for MedPointe's Tussi-12D. Thereafter, on November 25, 2003, MedPointe commenced this action requesting, inter alia, that this Court preliminarily and permanently enjoin Hi-Tech from "manufacturing, using, offering to sell or selling within the United States, or importing into

the United States, the Tannate 12d S product, and any other product that infringes or induces or contributes to the infringement of the '206 patent". (Compl., at ¶ B.)

Hi-Tech was prepared to ship several thousand orders of its Tannate-12DS when this Court entered an order preliminarily enjoining Hi-Tech from selling its Tannate-12DS until final judgment in this action. (Def. Br., at 5-6; Dkt. entry no. 26.) Nevertheless, Hi-Tech resumed selling Tannate-12DS after the Federal Circuit vacated the preliminary injunction order. (Def. Br., at 6; Dkt. entry nos. 54 & 55.)

**DISCUSSION**

**I. Legal Standards**

**A. Summary Judgment Standard**

Rule 56(c) provides that summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c) The party moving for summary judgment bears the initial burden of showing that there is no genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). Once the movant has met this prima facie burden, the non-movant "must set forth specific facts showing that there is a genuine issue for trial." Fed.R.Civ.P. 56(e). A non-movant must

present actual evidence that raises a genuine issue of material fact and may not rely on mere allegations. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986).

The Court must view the evidence in the light most favorable to the non-movant when deciding a summary judgment motion. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986). At the summary judgment stage, the Court's role is "not . . . to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." Anderson, 477 U.S. at 249. Under this standard, the "mere existence of a scintilla of evidence in support of the [non-movant's] position will be insufficient [to defeat a Rule 56(c) motion]; there must be evidence on which the jury could reasonably find for the [non-movant]." Id. at 252. "By its very terms, this standard provides that the mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no genuine issue of material fact." Id. at 247-48 (emphasis in original). A fact is material only if it might affect the action's outcome under governing law. Id. at 248. "[T]here is no issue for trial unless there is sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party. If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." Id. at 249-50 (internal citations omitted).

**B. Legal Standards Governing Hi-Tech's Obviousness Defense**

A patent is presumed to be valid, and each of its claims are presumed valid independent of the validity of other claims. 35 U.S.C. § 282. A party asserting the invalidity of a patent or one or more of its claims has the burden of establishing such invalidity, which is satisfied only by clear and convincing evidence. Id.; Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 446 (Fed. Cir. 1986). Clear and convincing evidence is evidence that proves in the mind of the trier of fact an abiding conviction that the truth of the factual contentions is highly probable. Intel Corp. v. U.S. Int'l Trade Comm'n, 946 F.2d 821, 830 (Fed. Cir. 1991).

Section 103 states in relevant part:

> A patent may not be obtained if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

35 U.S.C. § 103. Thus, a patent is invalid if "the difference between the new thing and what was known before is not considered sufficiently great to warrant a patent." Graham v. John Deere Co., 383 U.S. 1, 14 (1966) (quoting H.R. Rep. No. 1923, at 7 (2d Sess. 1952)).

The Court, in determining whether a claimed invention was obvious, must consider (1) the scope and content of the prior

art, (2) the differences, if any, between the prior art and the claims at issue, and (3) the level of ordinary skill in the pertinent art ("the primary Graham factors"). Graham, 383 U.S. at 17; Bausch & Lomb, 796 F.2d at 447. The Court should also consider secondary factors such as the patented invention's commercial success, whether the patent satisfied a long-felt but unmet need, and the failure of others. Graham, 383 U.S. at 17; Bausch & Lomb, 796 F.2d at 447. "It is black letter law that the ultimate question of obviousness is a question of law." Richardson-Vicks Inc. v. Upjohn Co., 122 F.3d 1476, 1479 (Fed. Cir. 1997).

The law presumes that all the prior art references are directly in front of the hypothetical person of ordinary skill. See In re Winslow, 365 F.2d 1017, 1020 (C.C.P.A. 1966). Accordingly, the Court cannot inquire into what patentees or inventors likely would have done when faced with the prior art references, but instead must consider only what a person with conventional wisdom in the pertinent art would have done. See Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 454 (Fed. Cir. 1985). Thus, the issue turns on whether the claimed subject matter, as a whole, would have been obvious to a person of ordinary skill at the time the invention was made. Union Carbide Corp. v. Am. Can Co., 724 F.2d 1567, 1575 (Fed. Cir. 1984); Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1566 (Fed.

Cir. 1987); In re Beattie, 974 F.2d 1309, 1311 (Fed. Cir. 1992) (explaining that claimed invention would have been obvious if "there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the [claimed] combination").

A suggestion or motivation to modify prior art teachings may be derived from the prior art itself, the knowledge of one of ordinary skill in the art, or the nature of the problem to be solved. Sibia Neurosci., Inc. v. Cadus Pharm. Corp., 225 F.3d 1349, 1356 (Fed. Cir. 2000). Indeed, the suggestion to make the claimed invention may be based upon the "common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference." In re Bozek, 416 F.2d 1385, 1390 (C.C.P.A. 1969). However, the motivation cannot come from the invention itself. This is particularly important "in the case of less technologically complex inventions, where the very ease with which the invention can be understood may prompt one 'to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.'" In re Dembiczak, 175 F.3d 994, 999 (Fed. Cir. 1999); see In re Rouffet, 149 F.3d 1350, 1358 (Fed. Cir. 1998) ("This court forbids the use of hindsight in the selection of references that comprise the case of obviousness."

**II. Legal Standards Applied Here**

Hi-Tech contends that applying the primary Graham factors here mandates the conclusion that the '206 patent is invalid for obviousness, and all relevant secondary considerations do not overcome this clear conclusion of obviousness. (Def. Br., at 8.) Specifically, Hi-Tech asserts that (1) the prior art, which includes Candettes and the prior art considered by the PTO, contains no genuine issues of material fact, (2) the parties agree that a person of ordinary skill in the applicable art "would have at least a B.S. degree, or its equivalent, in chemistry, pharmacology or pharmacy, and additional experience in the development and/or evaluation of drug products and therapies", (3) the differences between the prior art and the claimed invention are trivial, and (4) there was "irresistible motivation to combine and/or modify the prior art references to arrive at the invention of the '206 Patent via two separate but closely related routes: modifying Candettes and modifying Tussi-12." (Id. at 9, 12-13, & 17.) Further, Hi-Tech asserts that this Court did not find evidence of unexpected results in ruling on MedPointe's request for a preliminary injunction, and that "there was and is no legally cognizable evidence of 'failure of others' to buttress the validity of the '206 Patent." (Id. at 26 & 29.) However, Hi-Tech states that this Court may assume for purposes of deciding this motion that it and others copied MedPointe's patented invention and that MedPointe achieved some

level of commercial success by offering Tussi-12D. (Id. at 29 & 31.) Against this backdrop, Hi-Tech argues that this Court should hold that claims 1, 5-8, and 12-14 of the '206 patent are invalid for obviousness. (Id. at 37.)

MedPointe, in contrast, contends that Hi-Tech uses hindsight to reconstruct the patented invention from the prior art, but ignores the fundamental point that "even though all of the elements of the claimed inventions had existed separately and independently in the art for many years no one thought to make the patented invention before Dr. D'Addio." (Pl. Br., at 23-24.) MedPointe also contends that before the claimed invention was made, a person of ordinary skill in the art, who did not have the benefit of the claimed invention, would not have been motivated to create it. (Id. at 25.) Moreover, MedPointe argues that neither the prior art Tussi-12 nor Candettes renders the '206 patent invalid for obviousness. (Id. at 27 & 31.) Finally, MedPointe argues that the "nonobviousness of the '206 patent is confirmed by substantial real-world evidence", including that (1) its commercial embodiments have enjoyed great commercial success, (2) at least five generic companies have sought to copy Tussi-12D, (3) MedPointe has successfully asserted its '206 patent against three other generic companies that have attempted to copy its products, and (4) Tussi-12D met long-felt needs that had not been satisfied by other products on the market. (Id. at 38, 42,

43, & 45.) Thus, MedPointe asserts that a reasonable fact finder could rule in its favor, and summary judgment is inappropriate because genuine issues of material fact exist. (Id. at 46.)

Hi-Tech and MedPointe's conflicting assertions preclude summary judgment here because questions of material fact as well as issues of credibility and reliance exist. With respect to the primary Graham factors, the parties offer conflicting evidence regarding whether (1) the prior art Candettes employed the same ingredients in the form of nontannate salts as are recited in the '206 patent, (2) Hi-Tech's expert witness, Dr. O'Donnell appropriately analyzed the prior art and created an accurate table listing the active ingredients of various commercial cough and cold products, (3) ammonium chloride constituted an active ingredient in Candettes, (4) ammonium chloride is an effective expectorant, (5) phenylephrine hydrochloride is equally as effective as phenylephrine tannate or whether there are important differences in their pharmacokinetics, and (6) there were products available on the market prior to the date the '206 patent was issued containing nearly identical tannate combinations to those recited in claims 7 and 14 of the '206 patent. (Pl. Statement of Uncontested Facts, at ¶¶ 24, 33, 42-44, 46, 52, & 69-71; Def. Resp. & Counterstatement to Pl. Statement of Uncontested Facts, at 13, 18, 24-29, 31-32, & 42-45.) Thus, although the parties agree on the appropriate level

of ordinary skill in the art, this Court finds that questions of fact remain in dispute with respect to the scope and content of the prior art and the differences between the prior art and the invention claimed in the '206 patent. See Graham, 383 U.S. at 17; Bausch & Lomb, 796 F.2d at 447.

This Court also finds, based on the evidence presented by the parties, that genuine issues of material fact exist with respect to certain secondary factors relied upon by the parties. See Graham, 383 U.S. at 17 (noting that in determining whether claimed invention should have been obvious, courts should consider secondary factors such as commercial success, long-felt but unmet needs, and failure of others); Bausch & Lomb, 796 F.2d at 447. First, the parties dispute whether the Federal Circuit, in addressing Hi-Tech's appeal of this Court's grant of a preliminary injunction, definitively determined that there was no evidence that the invention claimed in the '206 patent was an unexpected result. (Pl. Statement of Uncontested Facts, at ¶ 58; Def. Resp. & Counterstatement to Pl. Statement of Uncontested Facts, at 35-36.) Second, the parties disagree as to whether MedPointe has provided evidence that Tussi-12D was better than its predecessors in any respect, and whether MedPointe's own prior art, Tussi-12, remains available for purchase. (Pl. Statement of Uncontested Facts, at ¶¶ 59 & 65; Def. Resp. & Counterstatement to Pl. Statement of Uncontested Facts, at 36 &

39.)[3] Therefore, because this Court concludes that genuine issues of material fact exist, this Court will deny Hi-Tech's s motion for summary judgment on patent invalidity.

**III. The Procedural Posture of This Action**

The ultimate determination of whether a patent is invalid for obviousness, as discussed supra, is a question of law for the Court. Hewlett Packard Co. v. Mustek Sys., Inc., 340 F.3d 1314, 1325 (Fed. Cir. 2003). However, the obviousness issue may be submitted to a jury where, as here, there are disputed factual issues. Id. Both parties have expressly requested a trial by jury in this action. (See Compl., at 6; Am. Ans. & Counterclaim, at 26.)[4]

The jury's resolution of the underlying factual disputes must be supported by "substantial evidence", but its legal determinations will be reviewed de novo in light of such factual

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[3] In this connection, Hi-Tech and MedPointe also dispute the scope and effect of Judge Lifland's findings regarding the validity of one of MedPointe's other patents. (Pl. Statement of Uncontested Facts, at ¶ 56; Def. Resp. & Counterstatement to Pl. Statement of Uncontested Facts, at 34-35.) See MedPointe Healthcare, Inc. v. Morton Grove Pharms., No. 01-5190 (D.N.J. Mar. 28, 2003). We express no opinion on that issue in ruling upon the present motion.

[4] At trial, the jury's verdict sheet may ask, inter alia, the following: (1) Do you find that Hi-Tech has proven by clear and convincing evidence that claims 1, 5-8, and 12-14 of the '206 patent are invalid because the subject matter of those claims would have been obvious in view of the prior art?, and (2) Do you find that MedPointe has proven by a preponderance of the evidence that Hi-Tech's Tannate-12DS infringes any claim of the '206 patent?

determinations. Id. Thus, to reach a verdict that the '206 patent is not invalid for obviousness, the jury must first make underlying factual findings that the prior art references presented into evidence were not analogous to, or did not supply the required suggestion or motivation to combine the ingredients recited in the claims of the '206 patent.

Either party may move for judgment as a matter of law ("JMOL") before the case is submitted to the jury. Fed.R.Civ.P. 50(a)(2). The Court may, however, reserve ruling on such a motion and submit the action to the jury "subject to the court's later deciding the legal questions raised by the motion." Id. at (b). The threshold question for the Court with respect to obviousness on a motion for JMOL is "whether the factual findings of the jury, expressed or implied in the verdict, are supported by substantial evidence in the record." Richardson-Vicks, Inc., 122 F.3d at 1478. After determining which, if any, factual findings are supported by substantial evidence, the Court must apply its judgment to the ultimate legal question of whether the claims at issue would have been obvious. Id. Thus, although this action will proceed to a trial by jury, the ultimate determination of whether the '206 patent is valid may be decided by this Court.

**CONCLUSION**

The Court, for the reasons stated supra, will deny Hi-Tech's motion for summary judgment on its counterclaim allegation that claims 1, 5-8, and 12-14 of the '206 patent are invalid for obviousness. The Court will issue an appropriate order and judgment.

s/ Mary L. Cooper
**MARY L. COOPER**
United States District Judge